

REMARKS

Claims 22-38, and 40-47 remain pending after entry of this amendment. Claims 22 and 38 were amended herein. Applicant respectfully asserts that the rejections be reconsidered in light of the amendments and comments offered herein.

Rejection Under 35 U.S.C. § 112

Claims 22-38 and 40-47 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Office Action notes that claims 22 and 38 inferentially include “an electrode connector” and it is unclear if the Applicant is positively reciting the element or functionally reciting the element. Although Applicant does not necessarily agree with this rejection, claims 22 and 38 were amended herein to positively recite an electrode connector. Applicant respectfully requests that this rejection be withdrawn.

Rejection Under 35 U.S.C. § 102

Claims 22-26, 29-31, 33, 34, 36-38, 40-43, 46, and 47 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hoffman (U.S. Patent No. 5,534,022). Applicant respectfully traverses this rejection.

The Office Action alleges that Hoffman shows the use of a distal electrode 38, coil electrode 20, proximal ring electrode 36, and another proximal ring electrode as element 20’ (Office Action, page 2-3).

Claims 22-26, 29-31, 33, 34, 36-38, 40-43, 46, and 47

With respect to the rejected claims, Applicant respectfully disagrees that the defibrillation electrode 20 of Hoffman is analogous to the coil stimulation electrode as recited in claim 22. The defibrillation electrode 20 of Hoffman is used alternatively for defibrillation and for sensing (Hoffman, column 5, lines 15-18). Specifically, it is stated by Hoffman that “the most distal 1 to 5 mm of the defibrillation electrode **20** is covered with a porous coating..., or otherwise has an increased surface area portion **26**, such as by etching or electrolytically roughening” (Hoffman, column 5, lines 27-32). The

defibrillation electrode in Hoffman is configured specifically to sense. Based on this distinction, Applicant respectfully disagrees that Hoffman anticipates claims 22-26, 29-31, 33, 34, 36-38, 40-43, 46, and 47.

Claims 29-30

With respect to claims 29-30, Applicant respectfully disagrees, as stated in the Office Action, that “Hoffman is capable of meeting the functional use recitations presented in the claims of being used for insertion through the sacrum into position for stimulation of one or more sacral nerves without causing damage since Hoffman’s lead is of a similar size (2.5 mm) and shape as the Applicant’s lead and Hoffman’s lead is very flexible and used in the veins and the heart” (Office Action, page 3).

Applicant disagrees that Hoffman’s lead is of a similar size. Hoffman’s lead body diameter is generally about 2.5 mm to 4.5 mm (Hoffman, column 6, lines 33-34). Contrary to that, the Applicant’s lead body diameter is generally in the range of about 0.5 mm to about 2 mm (US 2001/0025192, paragraph 0057). A lead with a diameter in the range of 2.5 mm to 4.5 mm is not “of a similar size” as a lead with a diameter in the range of 0.5 mm to about 2 mm.

Applicant also disagrees that Hoffman’s lead is necessarily “very flexible”. The specification of Hoffman is silent regarding the flexibility of the lead of Hoffman.

Applicant also disagrees with the implied assertion that because Hoffman’s lead is used in the veins and heart, may or may not be flexible, and may or may not be “of the same size”; it is capable of meeting the functional use recitations in claims 29 and 30. Because of the differences in the tissue types, and the differences in the anatomy between the veins and heart and the vicinity of the sacral nerves, a lead that is capable of providing therapy to a vein or heart would not necessarily be capable of providing therapy to the vicinity of the sacral nerves. The fact that a certain characteristic may be present in a prior art reference is not sufficient to show anticipation (MPEP § 2112).

Claim 31, 38, 40-43, 46, and 47

The Office Action states that Hoffman discloses another proximal ring electrode as element 20’. Applicant respectfully disagrees that element 20’ of Hoffman is analogous to a “third ring electrode”, as recited in claims 31, 38, 40-43, 46, and 47. The

element 20' of Hoffman is another defibrillation electrode (Hoffman, column 8, lines 39-41). The element 20' is discussed more specifically at column 8, lines 43-51. From that discussion it can be seen that 20' is the same as 20, a defibrillation electrode that can function to sense as well. As stated above, 20 is not analogous to the coil electrode as claimed herein, and is certainly not analogous to a ring electrode as claimed herein. Because **Hoffman does not teach a third ring electrode**, it does not anticipate claims 31, 38, 40-43, 46, and 47.

Based on the comments offered above, Applicant respectfully asserts that claims 22-26, 29-31, 33, 34, 36-38, 40-43, 46, and 47 are not anticipated by Hoffman because Hoffman fails to disclose all of the elements of the claims.

Rejection Under 35 U.S.C. §§ 102/103

Claims 28, 32, 35, and 45 are rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative under 35 U.S.C. § 103(a) as obvious over Hoffman. Applicant respectfully traverses this rejection.

Applicant reiterates the comments offered above with respect to Hoffman not disclosing a coil electrode as claimed herein. Applicant also asserts that one of skill in the art would not have been motivated to modify the lead of Hoffman to render it analogous to the lead of claims 28, 32, 35, and 45 by changing the coil electrode because doing so would render the lead of Hoffman unsuitable for its intended purpose.

With respect to claim 28, Applicant disagrees that Hoffman's lead is of a similar size. Hoffman's lead body diameter is generally about 2.5 mm to 4.5 mm (Hoffman, column 6, lines 33-34). Contrary to that, the Applicant's lead body diameter is generally in the range of about 0.5 mm to about 2 mm (US 2001/0025192, paragraph 0057). A lead with a diameter in the range of 2.5 mm to 4.5 mm is not "of a similar size" to a lead with a diameter in the range of 0.5 mm to about 2 mm. Furthermore, because the lead of Hoffman was intended to be used in an entirely different portion of the anatomy (heart and veins versus vicinity of sacral nerves) and an entirely different function (defibrillation and sensing versus stimulation), one of skill in the art would not have been

motivated to modify the size of the Hoffman lead because doing so could render it unsuitable for its intended purpose.

In light of the comments offered above, Applicant respectfully requests that the rejection of claims 28, 32, 35, and 45 under 35 U.S.C. § 102 or 103 be withdrawn.

Rejection Under 35 U.S.C. § 103

Claims 27 and 44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hoffman. Applicant respectfully traverses this rejection.

With respect to claim 44, Applicant reiterates the comments offered above with respect to claim 38, that Hoffman does not teach a third electrode.

The Office Action asserts that Hoffman discloses the claimed invention except for the length of the coil electrode; and further states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead as taught by Hoffman so that the length of the coil electrode was 0.1 to 1.5 inches (Office Action, page 5).

Applicant respectfully disagrees that such a modification would have been obvious because such a modification could have rendered the lead of Hoffman unusable for its intended purpose. According to MPEP § 2143.01(V), there can be no motivation to modify a reference if the proposed modification would render the prior art article unusable for its intended purpose.

In light of the comments offered above, Applicant respectfully requests that the rejection of claims 27 and 44 be withdrawn.

Conclusion

Applicant also notes that there may be other arguments which were not presented herein, and Applicant does not concede those arguments by not having presented them herein. Applicant also does not necessarily agree with the correctness of statements made in the Office Action that were not rebutted herein.

In view of the foregoing amendments, Applicants respectfully request reconsideration and allowance of the claims as all rejections have been overcome. Early notice of allowability is kindly requested.

The Examiner is respectfully requested to contact the undersigned by telephone at 651.259.6702 or by E-mail at anelson@cnwiplaw.com with any questions or comments.

Please grant any extension of time, if necessary for entry of this paper, and charge any fee due for such extension or any other fee required in connection with this paper to Deposit Account No. 50-3964.

Respectfully Submitted,

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/Anna M. Nelson/
Anna M. Nelson
Registration No. 48,935
Campbell Nelson Whipps, LLC
Historic Hamm Building
408 St. Peter Street
Suite 240
St. Paul, MN 55102